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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HUTSON, RICHARD G	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 04/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/996,952	WALKER ET AL.	
	Examiner	Art Unit	
	Richard G Hutson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *4-8 and 12-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 9-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants amendment of the specification, and the petition of the previous restriction requirement, in the paper of 12/12/2003, is acknowledged. Claims 1-20 are at issue and are present for examination.

Applicants' arguments filed on 12/12/20039, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

It is noted to applicants that the above referred to petition has been denied and a communication indicating such should have preceded this office action.

Election/Restrictions

Applicants comments regarding the previous restriction requirement and applicants traversal of this requirement as well as applicants reference to the potential rejoinder of nonelected claims are acknowledged. Applicants further reference to applicants submitted petition is also acknowledged. The denial of applicants petition is also acknowledged by the examiner.

Claims 4-8 and 12-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 9.

Specification

The disclosure is objected to because of the following informalities:

Figures 1 and 2 list sequences which do not appear to have associated with them a sequence identifier. Further, when a sequence is listed in a drawing, the sequence identifier for that sequence must also be listed in the drawing or in the description of the drawing.

> **MPEP Section 2422.02**, The Requirement for Exclusive Conformance; Sequences Presented in Drawing Figures states: "...It should be noted, though, that when a sequence is presented in a drawing, regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings."

In response to the above objection, applicants traverse that it is readily apparent and conventional in the art in polynucleotide translations such as those presented in the figures, to present the polynucleotide sequence that is identified in the description of the figure followed by its triplet codon encoded amino acid sequence below. While this may be true, it remains that the triplet codon encoded amino acid sequence is a sequence as defined by the sequence rules, and thus a "sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings".

Appropriate correction is required.

Claim Objections

Claims 2, 3 and 9-11 are objected to because of the following informalities:

Claim 2 (claims 3 and 9-11 dependent form) contain non-elected subject matter (i.e. SEQ ID NOs: 4 and 6). Applicants deferral to responding to this objection until a

time at which the submitted petition has been rendered is acknowledged. Applicants is reminded that applicants petition has now been denied.

Appropriate correction is required.

Claim Rejection(s) - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3 and 9-11 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The rejection is stated in the previous office action. In response to this rejection applicants have submitted three Declarations under 37 C.F.R. 1.132 along with respective attachments and ten scientific references and traverse the rejections in light of applicants submission.

The rejection of claims 1-3 and 9-11 under 35 U.S.C. 101 as set forth in item previously is maintained for the reasons of record and the reasons stated below.

It is the examiner's position that the asserted utilities for the claimed polynucleotide, polypeptide, and microarray are neither substantial nor specific. Applicants traverse on the basis that the rejection ignores the most important and obvious asserted utility for the claimed polynucleotides as surrogate markers for previously known genes associated with steroid synthesis in placental tissues, which are useful markers in the diagnosis, prognosis, treatment and evaluation of therapies for

disorders associated with pregnancy, particularly pregnancy-induced hypertension (PIH) and preclampsia. Applicants submit that based on the highly significant co-expression of SEQ ID NOs: 1-9 (SEQ ID NO: 7) with previously known placental steroid synthesis genes using "Guilt-by Association" analysis, that the statements that the disclosed use is generally applicable to any nucleic acid are contradictory. Applicants comments traversing the above rejection are acknowledged, however, not found persuasive because while applicants point out that the disclosed use of these nine sequences as surrogate markers for the eight known steroid synthesis markers is not one "generally applicable" to any nucleic acid, it remains what substantial utility there is in a proposed marker for the referred to eight placental steroid synthesis genes.

In support of applicants position of such a well-established utility, applicants submit three Declarations under 37 C.F.R. 1.132 with respective attachments and ten scientific references filed before the November 27 2000, priority date of the instant application (i.e. The Rockett Declaration, the Iyer Declaration, and the Bedilion Declaration) and applicants assert that these fully establish that it was well established in the art a number of points as outlined by applicants with respect to a well established utility.

Applicants traverse the instant rejection by arguing that the claimed polynucleotide has utility without requiring knowledge of the function of the encoded polypeptide. Applicants cite the Declaration of Dr. Tod Bedilion filed December 12, 2003 (hereafter referred to as the "Bedilion Declaration") in support of their argument and assert that the Bedilion Declaration demonstrates the utility rejection is without

merit. Applicants assert the Bedilion Declaration describes how the claimed polynucleotide can be used in gene expression monitoring systems that were allegedly well known at the time of the invention, and how those applications are useful in developing drugs and monitoring their activity. Applicants assert that the law has never required knowledge of biological function to prove utility and further assert the uses of the polynucleotide in gene expression monitoring applications are independent of its biological function. Applicants' argument is not found persuasive.

It is noted that Dr. Tod Bedilion is a consultant for Incyte Corporation and thus is a concerned party. Regarding the merit of the examiner's position, *any* polynucleotide can be used for gene expression monitoring and consequently, this asserted utility is *not* specific. Furthermore, the specification fails to provide guidance as to enable a skilled artisan to use data relating to the claimed polynucleotides derived from the results of toxicology testing and what the results would mean. For example, if the claimed polynucleotide was attached to a microarray and used in toxicology testing or gene expression analysis and a result showed that expression was increased when a cell was treated with a particular agent, the specification provides no basis on which a skilled worker would be able to determine whether that result is meaningful. As such, further experimentation would be required to interpret the results of such gene expression analysis and consequently, this asserted utility is *not* substantial. The examiner acknowledges that the utility requirement does not require knowledge of biological function. A claimed polynucleotide can meet the requirements of utility as long as the specification discloses a credible, specific and substantial asserted utility or a

well-established utility for the claimed polynucleotide, even though the function of the polynucleotide or encoded polypeptide is not disclosed in the specification. For example, Shattuck-Eidens et al. (US Patent 5,693,473) teach mutant alleles of the *BRCA1* gene that predispose a patient to developing breast and ovarian cancers (abstract). While there is no disclosure of the function of the mutant *BRCA1* genes or their gene products, the invention nevertheless has utility as being an indicator for susceptibility to developing breast and ovarian cancers. Contrary to this example, the instant specification fails to assert a specific and substantial utility for the claimed polynucleotide.

Applicants argue that in order to satisfy the utility requirement of 35 USC 101 and 112, first paragraph, the applicant need only show that the invention is "practically useful" and confers a "substantial", "specific benefit" on the public. Applicants cite the following case law that is allegedly relevant to the instant rejection: *Anderson v Natta*, 480 F.2d 1392, 1397, 178 USPQ 458 (CCPA 1973); *Brenner v Manson*, 383 US 519, 534-35, 148 USPQ 689 (1966); *Juicy Whip Inc. v Orange Bang Inc.*, 51 USPQ2d 1700 (Fed Cir 1999); *Stiftung v Renishaw PLC*, 945 F2d 1173, 1180, 20 USPQ2d 1094 (Fed Cir 1991); *Standard Oil Co. v Montedison, S.p.a.*, 212 USPQ 327 343 (3d Cir 1981); *Cross v Izuka*, 753 F2d 1040, 1048 (Fed Cir 1985); *Nelson v Bowler*, 626 F2d 853, 856, 206 USPQ 881 (CCPA 1980); *In re Cortright*, 165 F3d 1353, 1357, 49 USPQ2d 1464 (Fed Cir 1999); *In re Brana*, 51 F3d 1560, 1566; 34 USPQ2d 1436 (Fed Cir 1995); and *In re Langer*, 503 F2d 1380, 1391-92, 183 USPQ 288 (CCPA 1974). Applicants' argument is not found persuasive. The essential disagreement between the examiner's

position and applicants' position appears to be the interpretation of what constitutes a specific and substantial utility, as will be explained in detail below.

Applicants argue the claimed invention meets all necessary requirements for establishing a credible utility under the law as there are allegedly "well-established" uses for the claimed invention and there are allegedly specific practical and beneficial uses disclosed in the specification for the claimed invention as disclosed in the Bedilion Declaration and that objective evidence, allegedly not considered by the Office, further corroborates the credibility of the asserted utilities. Applicants' argument is not found persuasive.

The claimed invention has no well-established use and there is no specific and substantial use for the claimed invention. Each of applicants' asserted utilities for the claimed polynucleotide, *i.e.,* diagnosis of conditions and disorders characterized by expression of SEQ ID NOs: 1-9, for toxicology testing, and for drug discovery, will be addressed in detail below. Applicants do not elaborate on the "objective evidence" that has allegedly not been considered by the Office. Contrary to applicants' assertion, the examiner has fully considered ALL evidence of record in evaluating the claims for utility under 35 USC §§ 101 and 112, first paragraph.

Applicants argue the claimed invention has real-world utility as allegedly being useful for toxicology testing, drug development, and disease diagnosis through gene expression profiling, allegedly explained in the Rockett, Iyler and Bedilion Declarations, the substance of which is allegedly not rebutted by the Examiner. Applicants argue there is no dispute that the claimed invention is a useful tool in cDNA microarrays used

to perform gene expression analysis. Applicants assert that these uses are sufficient to establish utility for the claimed polynucleotides. Applicants argue the referred to Declarations explain the many reasons why a person skilled in the art reading the instant application would have understood this application to disclose the claimed polynucleotide to be useful for a number of gene expression monitoring applications, such as a probe for expression of the polynucleotide in connection with the development of drugs and the monitoring of the activity of such drugs. Applicants argue the examiner does not address the "fact" that the claimed polynucleotide can be used as highly specific probes to measure both the existence and amount of complementary mRNA sequences known to be expression products of the claimed polynucleotide. Applicants argue that the claimed invention is not some random sequence whose value as a probe is speculative or would require further research to determine. Applicants' arguments are not found persuasive.

It should be noted that the Bedilion Declaration has only been made of record with the amendment filed December 12, 2003 and therefore, the examiner has not had the opportunity to rebut the statements provided therein. The examiner agrees with the Bedilion Declaration to the extent that *any* polynucleotide, including the claimed polynucleotide, can be included as part of a cDNA microarray, however, this use does not confer patentable utility on the claimed polynucleotide as this utility is considered a general use and not a utility that is specific and substantial. MPEP § 2107.01 states, "A 'specific utility' is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention". Expressed

polynucleotides have a variety of general uses, *e.g.,* as a probe for hybridization or as a template for protein expression – these uses are applicable to *any* expressed polynucleotide and are not specific to the claimed polynucleotide. Also, the claimed polynucleotide has no substantial utility. MPEP § 2107.01 states, "Utilities that require or constitute carrying out further research to identify or reasonably confirm a 'real world' context of use are not substantial utilities". Because the specification fails to provide guidance to allow a skilled artisan to use data relating to the claimed polynucleotide derived from the results of gene expression analysis and what the results would mean, the results of gene expression monitoring assays would be meaningless without further research. In this case, the asserted use of the claimed polynucleotide for gene expression monitoring would be an assay to measure a polynucleotide that itself has no specific and substantial utility. MPEP § 2107.01 states that this utility is *not* substantial: "A method of assaying for or identifying a material that itself has no specific and/or substantial utility". Consequently, the claimed polynucleotides have no specific and substantial utility.

Applicants argue that because the claimed polynucleotidea are expressed, their utility as a measuring and analyzing instrument for expression levels is as indisputable as a scale's utility for measuring weight. Applicants cite case law as allegedly relevant to the patentable utility of research tools.

It is true that a scale, gas chromatograph, screening assays, and nucleotide sequencing techniques have utility as research tools. However, such tools present a result that requires no further experimentation for interpretation, *e.g.*, a scale provides

the weight of an object and requires no further experimentation for interpretation of the result. In the instant case, a more representative analogy to the claimed polynucleotide would be that of a scale without an identifiable unit of measure – one could place an object on the scale, however, further experimentation would be required to interpret the result and determine the weight of the object. Similarly, as applicants have provided no information regarding altered expression of the claimed polynucleotide or guidance for interpreting the results of gene expression analysis, additional experimentation would be required to interpret a result obtained using the claimed polynucleotide for gene expression analysis.

Applicants argue there can be no reasonable dispute that persons skilled in the art have numerous uses for information about relative gene expression including understanding the effects of a potential drug for treating various disorders. Applicants argue that, since the specification discloses the claimed polynucleotide is associated with various steroid synthesis genes, there can be no dispute that an ordinarily skilled artisan could put the claimed invention to such use, i.e., derive more information about relative gene expression than without it. Applicants' arguments are not found persuasive.

There is no evidence of record to suggest that the claimed polynucleotide has ANY association with ANY disease state. Applicants are invited to provide such evidence. However, in view of the lack of such evidence, such an association between the claimed polynucleotide and the stated disease states, *e.g.*, altered expression or polymorphism, does not exist. As stated above, any polynucleotide can be used for

gene expression analysis and the specification fails to provide guidance to allow a skilled artisan to use information relating to the claimed polynucleotide derived from the results of gene expression analysis and what the results would mean, the results of gene expression monitoring assays using a cDNA microarray comprising the claimed polynucleotide would be meaningless without further research. In this case, the asserted use of the claimed polynucleotide for gene expression monitoring would be an assay to measure a polynucleotide that itself has no specific and substantial utility. MPEP § 2107.01 states that this utility is *not* substantial: "A method of assaying for or identifying a material that itself has no specific and/or substantial utility". Consequently, the claimed polynucleotide has no specific and substantial utility.

Applicants argue the claimed polynucleotides are useful as tools for toxicology testing, drug discovery, and the diagnosis of disease and that these uses are "well-established". Applicants cite the references of Rockett et al. (*Xenobiotica* 29:655), Nuwaysir et al. (*Mol Carcinogen* l24 :153-159), Steiner et al. (*Tox Lett* 13 :467-471), Rockett et al. (*Environ Health Perspectives* 107:681), and an email from Dr. Cynthia Afshari to an Incyte employee, and examples (as set forth at the bottom of page 20 of the response filed December 29, 2003) that allegedly support applicants' assertions. Applicants argue that, because the examiner has allegedly failed to address or consider the "well-established" utilities for the claimed invention in toxicology testing, drug development, and disease diagnosis, the rejections should be withdrawn. Applicants' arguments are not found persuasive.

Each of these uses (toxicology testing, drug development, and disease diagnosis) will be addressed individually, because the facts and issues directed to each use are distinct and separable. First, applicants argue that toxicology testing is a well-established utility and concludes that the claimed polynucleotides could be used in this manner and that the claimed invention therefore possesses patentable utility. However, for a utility to be "well-established" it must be specific, substantial and credible. In this case all expressed polynucleotides have use in gene expression monitoring for toxicology testing and consequently, this utility is not specific. Furthermore, the specification fails to disclose the methods and information necessary for a skilled artisan to use the claimed polynucleotide for toxicology testing, *e.g.,* how would one interpret the results obtained from such testing? Therefore, this is a utility that would apply to virtually every member of a general class of materials, such as any collection of expressed polynucleotides. Such a utility is *not* specific and does *not* constitute a "well-established" utility. Moreover, use of the claimed polynucleotide in an array for toxicology screening is only useful in the sense that the information that is gleaned from the array is dependent on the pattern derived from the array, and says nothing with regard to each individual member of the array. Again, this is a utility that would apply to virtually every member of a general class of materials, such as any collection of polynucleotides. Even assuming *arguendo* that the expression of applicants' claimed polynucleotide was affected by a test compound in an array for drug screening, the specification does not disclose any guidance for interpretation of the result, and none is known in the art. Given this consideration, the claimed polynucleotide has no "well-

established" use. The artisan is required to perform further experimentation on the claimed material itself in order to determine to what "use" any expression information generated using this nucleic acid may have.

With regard to drug discovery and development, applicants mention gene expression profiling as one use of the claimed polynucleotide. Applicants refer to recent developments as providing evidence that the benefits of this information are already beginning to manifest themselves. However, applicants are incorrect in asserting that the efficacy (ability to produce a desired effect) of a compound could be evaluated from the result of a transcript image because there is no way to assess the meaning of any individual "hit" obtained from this procedure. The first requirement is that one must know the biological significance of the polynucleotide(s) which is/are being evaluated. Without this information, the results of the transcript image are useless because one would not inherently recognize how to interpret the result of increased or decreased polynucleotide expression or even what significance could be attributed to such changes in expression profiles. As such information has not been provided in the specification, further experimentation is required to identify a "real world" use for the claimed polynucleotide.

With regard to diagnosis of disease, in order for a polynucleotide to be useful, as asserted, for diagnosis of a disease, there must be a well-established or disclosed correlation or relationship between the claimed polynucleotide and a disease or disorder. The presence of a polynucleotide in tissue that also expresses one of a number of steroid synthesis genes is not sufficient for establishing a utility in diagnosis

of disease in the absence of some information regarding a correlative or causal relationship between the expression of the claimed polynucleotide and the disease. If a molecule is to be used as a surrogate for a disease state, some disease state must be specifically associated in some way with the molecule. In the absence of any disclosed relationship between the claimed polynucleotides or encoded proteins and any disease or disorder and the lack of any correlation between the claimed polynucleotides or the encoded proteins with any known disease or disorder, any information obtained from an expression profile would only serve as the basis for further research on the observation itself.

Applicants argue they have demonstrated that the claimed polynucleotides are associated with the expression of a number of steroid synthesis genes. However, it is noted that members of this gene family are structurally and functionally diverse and mere association of a polynucleotide with the expression of a gene family in no way provides evidence that the claimed polynucleotide is useful in treating ANY disorder – and the specification fails to provide guidance for using the claimed polynucleotide to diagnose or treat any such disorder.

Applicants argue that a "real-world" utility exists if actual use or commercial success can be shown. Citing case law, applicants state that such a showing of actual use or commercial success is conclusive proof of utility. Applicants argue that a vibrant market has developed for databases containing all expressed genes, including those of Incyte, the real party at interest. Applicants state Incyte's customers and the scientific community have acknowledged that Incyte's databases have proven valuable, and that

the databases including the claimed polynucleotide would be even more valuable. Applicants' arguments are not found persuasive.

The case law indicates that a rejection under 35 U.S.C. § 101 *for lack of operability* can be overcome by a showing of actual use or commercial success. The instant issue is whether or not the asserted utilities meet the three-pronged test for credibility, specificity, and substantiality. Such is not necessarily addressed by a showing of commercial success or actual use. Many products that lack patentable utility enjoy commercial success, are used, and are considered valuable, *e.g.*, a pet rock. In this case, applicants' asserted utilities are neither substantial or specific. Furthermore, while applicants present evidence showing that the database is commercially valuable, there is no evidence to suggest that the database is any more or less valuable with the inclusion of the *claimed* polynucleotide.

Applicants argue that, rather than responding to the evidence allegedly demonstrating utility, the examiner attempts to dismiss it altogether by arguing that the disclosed and well-established utilities for the clamed polynucleotides are not "specific and substantial asserted" utilities. Applicants argue the examiner is incorrect both as a matter of law and as a matter of fact. Applicants' arguments are not found persuasive.

It is the examiner's position that the claimed invention has no well-established use and there is no specific or substantial use for the claimed invention, even after FULL consideration of the "evidence" as provided in the specification. Applicants' arguments will be addressed in detail below.

Applicants argue that the examiner's rejection is based on the grounds that, without information as to the biological role of the claimed polynucleotide, the claimed invention lacks specific patentable utility. Applicants argue that, according to the examiner applicants are required to provide a specific and substantial interpretation of the results generated in an expression analysis. Applicants argue that specific and substantial interpretations regarding biological function are not necessary for obtaining a US patent. Applicants state the relevant question is not how or why the invention works, but whether the invention provides an "identifiable benefit" in currently available form. Applicants argue that the present invention meets this test. Applicants argue that the threshold for patentable utility is low and that only throwaway utilities are insufficient. Applicants' arguments are not found persuasive.

It is noted that applicants' arguments have mischaracterized the examiner's position. The examiner has fully considered applicants' "evidence" allegedly demonstrating utility and, in accordance with 35 USC § 101 has determined the claimed invention to lack patentable utility as the asserted utilities are neither specific nor substantial. The rejection never states that the precise biological role of a polynucleotide is required for it to possess patentable utility. The examiner acknowledges applicants' assertion that biological function of a polynucleotide need not be disclosed for a claimed polynucleotide to have patentable utility (see the example of Shattuck-Eidens et al. in US Patent 5,693,473 as described above). However, the specification fails to provide sufficient guidance such that one of ordinary skill in the art can use the claimed polynucleotide as a disease marker or for toxicology testing, drug discovery, or disease

diagnosis and as such, there is no specific and substantial asserted utility. For example, if the claimed polynucleotide were used in a microarray for toxicology testing and if a compound caused the claimed polynucleotide to be expressed at a decreased level as demonstrated by the data generated using the microarray, what information does this provide, other than to initiate further experimentation? In view of the specification, a skilled artisan would recognize that the determination of whether a compound is potentially therapeutic or deleterious requires significant further research, and thus the asserted utility is not substantial. Also, *any* expressed polynucleotide *can* be used in a microarray – just as any polynucleotide can be used for protein expression and thus the asserted utility is also not specific.

Even assuming *arguendo* that one of ordinary skill in the art could have used the claimed polynucleotide for diagnosing and/or treating a disease – which one cannot – one of ordinary skill in the art would have recognized the necessity of determining which of the asserted functions – if the claimed polynucleotide has any function, as it is just as likely that it is non-functional – is necessary in order to diagnose or treat a particular disease. There is no evidence of record that the claimed polynucleotide is involved in ANY disease state and it is just as likely that it is not. In view of the failure of the specification to provide a correlation of the claimed polynucleotide to a specific disease state and the necessary guidance for using the claimed polynucleotide to diagnose and treat a specific disorder, significant further research would be necessary for the skilled artisan to use the claimed polynucleotides in a real world context, and thus the asserted utility is not substantial.

Applicants argue the rejection is incorrectly based on the grounds that the use of an invention as a tool for research is not a substantial use. Applicants state that only a limited subset of research uses are not substantial: those in which the only known use for the claimed invention is to be an object of further study, thus merely inviting further research. Applicants argue that nowhere in their cited case law is it stated or implied that a material cannot be patentable if it has some other, additional beneficial use in research. Applicants argue the claimed invention has a beneficial use in toxicology testing, drug discovery, and disease diagnosis. Applicants argue the claimed polynucleotide is a tool not an object of research. Applicants argue the data generated as a result of gene expression monitoring using the claimed invention is not merely to study the polynucleotide itself, but to study properties of tissues, cells, and potential drug candidates and toxins. Applicants argue that without the claimed invention, information regarding properties of tissues, cells, and potential drug candidates and toxins is less complete. Applicants argue the invention has numerous additional uses as a research tool including diagnostic assays, chromosomal markers, ligand screening assays and drug screening.

As discussed above, whereas a scale or gas chromatograph has patentable utility as a research tool as providing a result that can be readily used and provides a specific benefit in currently available form, in this case, the claimed polynucleotide does NOT provide a specific benefit in currently available form and the asserted uses of the claimed polynucleotide either apply to the general class of polynucleotides (chromosomal marker) and/or would require further experimentation as described above

(diagnostic assay, ligand screening assay, and drug screening). The claimed polynucleotide is not disclosed as having a property that can be identifiably and specifically useful without further, additional experimentation. The claimed invention is, in fact, the object of further study, merely inviting further research. For example, the specification provides no guidance to allow a skilled artisan to use data relating to the claimed polynucleotide derived from the results of toxicology testing and what the results would mean. For example, if the claimed polynucleotides were attached to a microarray and used in toxicology testing or gene expression analysis and a result showed that expression was increased when a cell was treated with a particular agent, the specification provides no basis on which a skilled worker would be able to determine whether that result is meaningful. As such, further experimentation would be required to interpret the results of such gene expression analysis. Contrary to applicants' assertions, none of the asserted utilities for the claimed polynucleotide is specific and substantial.

Applicants challenge the legality of the Patent Examination Utility Guidelines. Applicants argue that "unique" or "particular" utilities have never been required by the law and applicants are unaware of any court that has rejected an assertion of utility on the grounds that it is not "particular" or "unique" to the specific invention. Applicants argue that to meet the utility requirement, the invention need only by "practically useful" and confer a "specific benefit" on the public. Applicants' arguments are not found persuasive.

Regarding the Training Materials, applicants are reminded that the examiner must examine a patent application according to the guidelines set forth by the USPTO as well as the MPEP, since the examiner has no authority to disregard such guidelines or to apply his own interpretation of patent law in the examination of the application. Furthermore, as set forth in the guidelines and the MPEP, the guidelines were promulgated by the Patent Office in accordance with all applicable case law and thus are believed to be consistent therewith. Applicants are further reminded that the examiner has no authority to comment in regard to the legality of the new utility guidelines or the MPEP as set forth by the USPTO. Accordingly, it is the examiner's position that the instant claims, based on an analysis of the utility requirement of 35 USC § 101 and following the current Utility Guidelines, have no specific, substantial, or credible utility.

Regarding applicants' comments regarding a "unique" utility, it is noted that applicants' characterization of the examiner's position is somewhat misleading. Applicants have never been asked to identify a utility that is unique, i.e., not shared by any other compounds or compositions. Rather, applicants have been required to identify a utility that is specific to the invention claimed, as opposed to one that would apply regardless of the specific properties of the claimed invention. An invention certainly can have a utility that is shared by other compounds or compositions. While a utility need not be unique to a claimed invention, it must nonetheless be specific, and in currently available form, in order to satisfy 35 USC § 101.

Thus for all of the reasons discussed above applicants argument is not found persuasive and claims 1-3 and 9-11 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 9-11 are ejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As discussed above under the rejection under 35 U.S.C. 101, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Applicants traverse this rejection based on the reasons stated above under 35 USC 101. For the reasons stated above applicants traversal is not found persuasive.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (571) 272-0930. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rgh
4/1/2004